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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,773	01/26/2001	George Verlaan	05032-00009	7775
7590	02/11/2004		EXAMINER	
John P. Iwanicki BANNER & WITCOFF, LTD. 28 State Street, 28th Floor Boston, MA 02109			KWON, BRIAN YONG S	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 02/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/770,773	VERLAAN ET AL.	
	Examiner	Art Unit	
	Brian S Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 October 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-13,15-39,41,42 and 44-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-12,17-39,41,42 and 44-86 is/are rejected.
- 7) Claim(s) 13,15 and 16 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Summary of Action

- I. The rejection of claims 44-45 under 35 USC 112, first paragraph, will not be maintained in light of the amendment.
- II. The rejection of claims 44-45 under 35 USC 101 will not be maintained in light of the amendment.
- III. The rejection of claims 1-2, 5-8, 11, 23-24, 29, 32-35, 37, 39, 41-42 and 44-45 under 35 USC 102(b) as being anticipated by Simone (US 5397786) will not be maintained in light of the amendment.
- IV. The rejection of claims 1, 5-8, 11-12, 17-24, 29, 32 and 41-42 under 35 USC 102(b) under 35 USC 102(b) as being anticipated by Hageman (WO 99/0335) will not be maintained in light of the amendment.
- V. The rejection of claims 3-4, 9-10, 12, 17, 19, 21, 30-31, 36 and 38 under 35 USC 103(a) as being unpatentable over Simone (US 5397786) will not be maintained in light of the amendment.
- VI. The rejection of claims 20 and 22 under 35 USC 103(a) as being unpatentable over Simone (US 5397786) in view of Kampinga et al. (US 6455511 B1) will not be maintained in light of the amendment.
- VII. Applicant's amendment necessitated a new ground of rejection(s) in this Office Action. The scope of the instant invention has been narrowed by applicant's amendment, which excludes a methyl amine as a sole active ingredient in said composition.

Status of Application

1. By Amendment filed October 29, 2003, Claims 14, 40 and 43 have been cancelled; Claims 1, 6, 8-10, 13, 15, 18, 26, 33, 35, 37, 39 and 44-45 have been amended; and Claims 46-86 have been newly added. Claims 1-13, 15-39, 41-42, 44-86 are currently pending for the prosecution on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
2. Claims 1-12, 17-24, 26-27, 29-39, 41-42 and 44-86 are rejected under 35 USC 103(a) as being unpatentable over Simone (US 5397786) and Thomas et al. (US 5972985), and if necessary, further in view of Kampinga et al. (US 6455511 B1).

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The newly amended claims read on composition comprising a methyl amine, flavanolignan, one or more digestible carbohydrates and one or more minerals, wherein said fluid has an essentially hypotonic osmolarity.

Simone teaches or suggests a hypotonic rehydration drink, comprises 1 to 30mg of betaine and methionine, choline, 1 to 100g of carbohydrates (e.g., glucose, maltodextrins, fructose, ribose, mannose, etc...), 2 to 2500mg of minerals (e.g., magnesium, calcium, sodium, potassium, etc...), vitamins (e.g., vitamin C, vitamin E, etc...), wherein said composition is useful for treating dehydration symptoms due to exposure to high temperature and/or heavy physical exercise, severe diarrhea or vomiting for a variety of causes such as gastrointestinal disorders, cardiovascular disorders, and chronic illnesses such as cancer (column 2, line 45 thru column 4, line 22; Table 1; column 5, lines 37-55; Claims 13-14 and 17-18).

Thomas teaches or suggests the use of the claimed flavanolignan (i.e., silybin or milk thistle) in a rehydration solution comprising histidine, vitamins (i.e., vitamin C, ascorbate, vitamin E, beta-carotene, vitamin A), glycerol, minerals (i.e., copper, iron, magnesium, manganese, zinc, iron, selenium) and lipoic acid (abstract; column 7, line 25; column 9, line 60 thru column 11, line 22; column 11, lines 33-35). The reference also teaches or suggests that said flavanolignan (i.e., silybin or milk thistle) would enhance the effects of ascorbate or vitamin C and protect the vascular system and strengthen the tiny capillaries that carry oxygen and essential nutrients to all cells (column 7, lines 17-18 and 35-37).

Kampinga teaches or suggests a rehydration composition containing trehalose, saccharides (e.g., glucose, fructose, mannose, galactose, sucrose, maltose, lactose, maltodextrins and glucose polymers), minerals (e.g., calcium, magnesium, zinc, iron, etc...), vitamins and

amino acids, wherein said composition is prepared in either isotonic or hypotonic solution (column 4, lines 51-64; claims).

The teaching of Simone differs from the claimed invention in (i) the use of flavanolignan (i.e., silybin) in said composition; (ii) the specific osmolarity of said composition; (iii) the specific dry mass content of ingredients in said composition; (iv) the specific amounts of active and inactive ingredients in a composition; (v) the specific mixtures of carbohydrates in a composition; (vi) the specific pH of the claimed invention; (vii) the administration of the claimed composition before, during or after the subject is undergoing surgery; (viii) the administration of said composition to elderly person; and (ix) the incorporation of zinc and iron in said composition. However, it would have been obvious to a person skill in the art, at the time of the invention was made, to arrive at the claimed invention containing all the ingredients herein (a methyl amine, flavanolignan, vitamins, carbohydrates, glycerol, minerals, lipoic acid, etc...). All the ingredients employed herein are known to be useful in preparing rehydration drink or solution.

In addition, it would have been apparent to those skilled in the art to optimize amounts of known active and inactive ingredients in a composition; the specific pH of the final composition; the dry mass of the ingredients in a composition; the specific mixtures of known digestible carbohydrates (e.g., glucose, fructose, galactose, mannose, ribose, inositol); and concurrent administration regimens as determined by good medical practice and the clinical condition of the individual patient.

Although the instant claims use the different names for the said ingredients than those taught in the cited references, these references are particularly pertinent and relevant because all

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the claimed species and their roles are well taught in the cited reference. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

3. Claims 25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simone (US 5397786) in view of Thomas et al. (US 5972985) and Kuznicki et al. (US 5464619).

The teaching of Simone has been discussed in above 35 USC 103(a) rejection.

The teaching of Thomas has been discussed in above 35 USC 103(a) rejection.

Kuznicki teaches or suggests a rehydration composition containing flavanols, electrolytes, carbohydrates or carbohydrate derivatives (e.g., fructose, glucose, maltodextrin, glycerol), caffeine and vitamins (abstract, column 4, lines 53-61; column 6, lines 37-44).

The referenced teaching differs from the claimed invention in the use of caffeine in said composition. To incorporate such teaching into the teaching of Simone, would have been obvious in view of Kuznicki who teaches or suggests the use of caffeine in rehydration solution.

Above references in combination makes clear that the use of caffeine and glycerol in rehydration solution is old and well known. Above references in combination makes clear that the formulation containing betaine, methionine, one or more digestible carbohydrates (e.g., glucose, fructose, galactose, mannose, ribose and inositol), minerals, caffeine, glycerol and vitamins are old and well known.

Allowable Subject Matter

4. The examiner indicated allowable subject matter in the Office Action mailed July 29, 2003 with the intention of allowing a composition comprising flavanolignan such as silibin and

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silymarin as the sole active ingredient (more specifically a composition consisting essentially of flavanolignan such as silibin and silymarin) in said composition. However, it appears in view of the amendment that applicant misunderstood the examiner's intention. The newly amended claims and added claims are not ready for the allowance.

Conclusion

5. Applicant's amendment necessitated a new ground of rejection(s) in this Office Action.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

**ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600**

A handwritten signature in black ink, appearing to read "Zohreh Fay".